

In the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application.

1. (Currently Amended) A method ~~of determining patient compliance in taking~~ to determine whether a patient has taken a medication, comprising

providing to a patient a ~~combination of a~~ medication comprising a combination of at least one active therapeutic agent and a marker, which is not chemically part of the active therapeutic agent itself, detectable in gaseous exhaled breath, the combination to be taken by the patient as a result of the patient's own actions, said combination being such that said marker and said at least one therapeutically active agent are taken by said patient concurrently;

obtaining a sample of the patient's gaseous exhaled breath;  
analyzing the sample of the patient's breath utilizing an instrument adapted to detect said marker detectable in gaseous exhaled breath to ascertain the presence or absence of said ~~odorous~~ marker in the patient's breath, where the presence of the marker is an indication that the patient has taken ~~of patient compliance in taking the medication~~ and the absence of the marker is an indication that the patient has not taken ~~of patient non-compliance in taking~~ the medication; wherein the medication is to be taken by volitional patient action at specified times;  
and,

based on the analysis, determining whether the patient has taken ~~was compliant in taking the medication or not.~~

2. (Canceled)

3. (Canceled)

4. (Previously Presented). The method of claim 1 wherein the sample of the patient's breath is analyzed to ascertain the presence or absence of said marker by sensor technology selected from the group consisting of semiconductor gas sensor technology and conductive polymer gas sensor technology.

5. (Previously Presented) The method of claim 4 wherein if the marker is present in the sample of the patient's breath, the sensor technology produces a unique electronic fingerprint which is an indication of the presence of the marker in the patient's breath.

6. (Previously Presented) The method of claim 1 wherein the marker is selected from trans-Anethole (1-methoxy-4-propenyl benzene) - anise; Benzaldehyde (benzoic aldehyde) - bitter almond; Butyl isobutyrate (n-butyl 2, methyl propanoate) - pineapple; Cinnamaldehyde (3-phenylpropenal) - cinnamon; Citral (2-trans-3, 7-dimethyl-2, 6-octadiene-1-al) - citrus; Menthol (1-methyl-4-isopropylcyclohexane-3-ol) - menthol; and alpha-Pinene (2, 6, 6-trimethylbicyclo-(3,1,1)-2-heptene) - pine.

7. (Previously Presented) The method of claim 1 wherein the sample of the patient's breath is analyzed to ascertain the presence or absence of said marker by a spectrophotometer.

8. (Previously Presented) The method of claim 1 wherein the sample of the patient's breath is analyzed to ascertain the presence or absence of said marker by a mass spectrometer.

9. (Original) The method of claim 1 wherein the marker is an additive combined with the medication.

10. (Previously Presented) The method of claim 1 wherein the marker is provided with the medication in the form of a coating on the medication.

11. (Original) The method of claim 10 wherein a substance to stimulate salivation is included with the marker.

12. (Currently Amended) The method of claim 1 wherein said providing comprises providing the marker ~~is included with a liquid medication with said medication as a liquid.~~

13. (Currently Amended) The method of claim 1 wherein said providing comprises providing the marker with said medication for the patient to take via the lungs~~is included with a pulmonary delivered medication.~~

14. (Currently Amended) The method of claim 1 wherein said providing comprises providing the marker with said medication for the patient to take~~is included with an intranasally delivered medication.~~

15. (Currently Amended) The method of claim 1 wherein said providing comprises providing the marker is with said medication for the patient to take intravenously ~~delivery included with intravenously delivered medication.~~

16. (Previously Presented) The method of claim 1 further

comprising the step of recording results regarding the presence or absence of the marker as provided from the analysis of the sample of the patient's breath.

17. (Previously Presented) The method of claim 16, further comprising the step of transmitting the results from the analysis of the sample of the patient's breath to an individual interested in the results.

18. (Previously Presented) The method of claim 1 where the analysis of the sample of the patient's breath includes comparing any marker sensed in the sample of the patient's breath with a predetermined signature profile of a specific marker.

19. (Original) The method of claim 18 wherein the predetermined signature profile of a specific marker is associated with a specific drug.

20. (Original) The method of claim 18 wherein the predetermined signature profile of a specific marker is associated with a class of drugs.

21. (Original) The method of claim 1 further comprising the step of capturing the sample of the patient's breath in a vessel prior to analysis.

22. (Original) The method of claim 1 further comprising the step of dehumidifying the sample of the patient's breath prior to analysis.

23. (Currently Amended) The method of claim 1 wherein the

marker, ~~in order to be~~ is not detectable, ~~must~~ unless it first reacts with enzymes in the patient's mouth.

24. (Currently Amended) The method of claim 1 wherein the marker, ~~in order to be~~ is not detectable, ~~must~~ unless it first reacts with acids in the patient's stomach ~~to be detectable~~.

25. (Currently Amended) The method of claim 1 wherein the marker, ~~in order to be~~ is not detectable, ~~must~~ unless it first be is absorbed in the patient's gastrointestinal tract and then is ~~be~~, at least partially, excreted from the lungs.

26. (Currently Amended) The method of claim 1, further comprising: if it is determined that the patient did take ~~was compliant in taking~~ the medication, analyzing the sample of the patient's breath to ascertain the concentration of said marker in the patient's breath.

27. (Currently Amended) The method of claim 1 further comprising identifying a baseline marker spectrum for the patient at a time prior to a time at which it is desired to ascertain whether a patient has taken ~~been compliant in taking~~ a medication.

28. (Canceled)

29. (Currently Amended) A method of producing medication which is detectable as an indication of patient compliance in taking the medication comprising the steps of:

identifying marker substance detectable in gaseous exhaled breath, and

combining a medication with said detectable marker substance,

wherein said medication is to be taken by volitional patient action at specified times whereby subsequent analysis of the patient's breath will confirm the presence or absence of said marker substance and thus indicate whether the patient has complied in taking said medication, wherein said combining comprises a step selected from the group consisting of: providing said marker as a coating to or physically combining said marker with said medication for administration in the form of pills, capsules, and fast-dissolving tablets, and admixing said marker with said medication for administration in a liquid form selected from oral administration of a syrup or via inhalation.

30. (Currently Amended) The method of claim 1 wherein said providing comprises providing the marker ~~is included with a medication for the patient to take transdermally adapted for transdermal delivery.~~

31. (canceled)

32. (Previously Presented) The method of claim 1 wherein the marker is a combination of markers combined as an additive with the medication.

33. (Currently Amended) The method of claim 1 wherein more than one ~~medication~~ therapeutically active agent is included in the medication.

34. (Previously Presented) The method of claim 1 wherein the

marker is an olfactory marker or an odorous compound.